


# **EXHIBIT 76**

## STANDARD OPERATING PROCEDURE

	Title: <b>CUSTOMER DUE DILIGENCE VISITS</b>	
No.: <b>DEA-53013</b>	Version: <b>00</b>	Effective: <b>12/23/2013</b>
Department: <b>DEA COMPLIANCE</b>		

**PURPOSE:** The purpose of this SOP is to provide guidance for Qualitest employees and/or third party contractors investigating Qualitest primary and secondary customers for the potential risk of diversion of Controlled Substances and/or List 1 Chemicals.

**SCOPE:** This SOP applies to all Qualitest customers and secondary customers identified through chargeback data and/or other intelligence.


**DEFINITIONS:**

Investigator	A person authorized by the Qualitest Director, DEA Compliance or Manager, Customer Due Diligence & SOM to conduct customer due diligence site visits. This includes Qualitest employees and third party contractors.
Suspicious Order	An order for a Controlled Substance or List 1 chemical which is of an unusual size, frequency, and/ or deviates substantially from a normal pattern.
Boundary	Monthly maximum dosage unit quantity for each immediate precursor or DEA base code of a drug or other substance that is customer specific.
Controlled Substance	A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V in Title 21 U.S.C.
List 1 Chemical	A chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of Title 21 U.S.C. and is important to the manufacture of the controlled substance.

**RESPONSIBILITY:** The SOM team has the primary responsibility for compliance with this SOP.

**SAFETY:** N/A

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REFERENCES: Identifying, Blocking and Reporting Suspicious Orders SOP

ATTACHMENTS: N/A

## PROCEDURE:

### I. Typical reasons for site visits


- A. Customer due diligence site visits shall be considered under the following circumstances:
  1. SOM team requests a visit when more information is needed in approving a new customer account request for Controlled Substances or List 1 Chemicals.
  2. SOM team requests a visit based on analysis and/or investigation findings.
  3. SOM Advisory Board requests a visit during monthly review of customers.
  4. SOM team requests a visit when a customer requests to begin ordering Controlled Substances, List 1 Chemicals or is seeking a boundary increase.

### II. Conducting Site Visits

- A. Investigators must schedule and complete the site visit within a reasonable amount of time from the request.
- B. The completed site visit report must be submitted within a reasonable period of time after the visit is concluded. The Director, DEA Compliance or Manager, Customer Due Diligence & SOM will determine a reasonable period of time based on factors such as the number of customers visited, and locations.
- C. Investigations are scheduled with the owner or Pharmacist in Charge (PIC), and are conducted at the customer's DEA registered location.
- D. All visits must be documented on the appropriate checklist based on the customer class of trade. All requested documentation will be collected; including dispensing records void of patient identifying information.
- E. Reports must be submitted to the Director, DEA Compliance and Manager, Customer Due Diligence & SOM for review. The reports must be uploaded to the repository as part of the customer's file pursuant to the Record Retention Policy.

### III. Investigation


- A. The Investigator will be given all pertinent information about the customer prior to the visit.

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- B. The investigator must document obvious signs of potential diversion including but not limited to:
1. Illicit drug use or transactions outside and around pharmacy
  2. Long lines of people waiting at the pharmacy
  3. Lack of a front end inventory
  4. Significant number of out-of-state vehicles parked at pharmacy
  5. FedEx or UPS shipping materials that could be evidence of internet activity
- C. The actual numbers must be obtained from the customer (if unavailable the owner or PIC provides an estimate) when asking the following questions:
1. Average number of all prescriptions filled per day, week, or month
  2. Average number of Controlled Substance prescriptions per day, week or month
  3. If percentage of Controlled Substances vs. non controlled substances is greater than 15% ask for an explanation.
  4. Percentage of prescriptions paid in cash (if greater than 10% ask for an explanation)
- D. The names and DEA numbers for the top 5-10 prescribers of all Controlled Substances as well as those in question must be obtained. Also obtain the name and DEA numbers for the top 5-10 prescribers of hydrocodone, oxycodone, alprazolam and other known highly diverted drugs as directed by the SOM Team.

#### IV. Investigation Review

- A. The Director, DEA Compliance or Manager, Customer Due Diligence & SOM will review the findings. The Investigator may be consulted during this process.
- B. If it is determined that there is significant risk of potential diversion, action may be taken against the customer after review by the Advisory Board. This may include denial of the new customer's application for purchasing Controlled Substances or discontinuing the sale of Controlled Substances with an existing customer or blocking the customer from ordering Controlled Substances and List 1 Chemicals. Any customer that is dropped due to significant risk of diversion will be reported to DEA.

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- C. Prompt notification is sent to the sales team, customer service and the customer by the Director DEA Compliance or the Manager, Customer Due Diligence & SOM.
- D. Customers that have been blocked from ordering Controlled Substances and List 1 Chemicals may request to have their ability to order Controlled Substances and List 1 Chemicals reinstated. Consideration of reinstatement of the customer will be made after a reasonable period of time has passed and after the reasons for the block have been mitigated as established by the SOM Team. The SOM Advisory Board will review all pertinent information for account reinstatement during the next scheduled SOM Advisory Board meeting. A significant investigation and remediation detail must be provided before reinstating the customer's Controlled Substance ordering ability.

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END SOP

REVISION HISTORY:  
REV00 – New SOP